

Agenda July 13, 2000
Joint Meeting - Nonprescription Drugs Advisory Committee &
Endocrinologic and Metabolic Advisory Committee

Food and Drug Administration: Center for Drug Evaluation and Research
Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD

Mevacor® NDA 21-213, lovastatin, 10mg, Merck and Company

8:00 Call to Order, Introductions

Eric Brass, M.D., Chair

Conflict of Interest Statement

Sandra Titus, Ph.D., Executive Secretary, NDAC

8:10 Open Public Hearing

9 :10 Opening Comments:

David Orloff, M.D., Deputy Director, DMEDP

9 :15 Merck and Company Presentation

Introduction

Eve Slater, M.D.

Benefit of lovastatin in an OTC Population

Polly Beere, M.D., Ph. D.

Safety of lovastatin

Scott Korn, M.D.

Label Development, Consumer Behavior and Overall Summary

Edwin Hemwall, PhD

10:45 Break

11:00 FDA Presentation

Introduction of Issues and Medical Review

Mary H. Parks, M.D., Medical Officer, DMEDP

Use Trials

Andrea Leonard Segal, M.D., Medical Officer, DOTCDP

Label Comprehension

Karen Lechter, J.D., Ph.D., DDMAC

12:30 Lunch

1:30 Charge to Committee

Linda Katz, M.D., MPH, Deputy Director, DOTCDP

1:45 Discussion and Questions

5:00 Adjourn